In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 22-557V

JOSE SANCHEZ,

Chief Special Master Corcoran

Filed: September 4, 2024

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Petitioner,

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Eleanor Hanson, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On May 23, 2022, Jose Sanchez filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner filed an amended petition on August 28, 2023. ECF No. 24. Petitioner alleges a Table claim – that he suffered a right shoulder injury related to vaccine administration ("SIRVA") after receiving a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine on May 28, 2021. *Id.* The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

A disputed fact issue has arisen regarding whether Petitioner's injury meets the Act's severity requirement. For the reasons discussed below, I find it more likely than not that Petitioner suffered the residual effects of the injury for more than six months.

¹ Because this fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

In March 2023, approximately ten months after the instant claim was initiated, Petitioner filed his vaccine administration record, medical records, and an affidavit, followed by a statement of completion. ECF Nos. 14-20. Prior to this case's activation to SPU, Petitioner filed an additional affidavit, an amended petition, and an amended statement of completion. ECF Nos. 21-25.

On February 26, 2024, Respondent stated he had completed the medical review of this matter and would defend the claim. ECF No. 29. Respondent thereafter filed a Rule 4(c) Report (ECF No. 31), contending that Petitioner has not established that he suffered his alleged SIRVA for more than six months post vaccination because his treatment appeared to cease five and a half months post vaccination. *Id.* at 5 (citing Ex. 6 at 67-72). More so, Petitioner attended six medical visits after his last visit for right shoulder pain (with "relevant providers" including his orthopedist and primary care provider ("PCP")) but did not mention shoulder-related complaints at any of these visits. *Id.* (citing Ex. 2 at 96-97; Ex. 4 at 13-20, 24-33, 35-43; Ex. 7 at 9-14). Respondent argues Petitioner's word alone is not sufficient to satisfy the severity requirement. *Id.* (citing Ex. 4 at 35; Ex. 10 at 3). Petitioner submitted updated medical records in summer 2024. ECF Nos. 32-35.

II. Relevant Authority

Pursuant to Section 13(a)(1)(A) of the Vaccine Act, a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies

between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed, or varied, by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Finding of Fact Regarding Severity

I make this finding after a complete review of the record to include all medical records, affidavits, and additional evidence filed, and in particular the following:³

 Petitioner received the Tdap vaccine intramuscularly in his right deltoid on May 28, 2021. Ex. 1 at 10; Ex. 9 at 2.

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³ While I have reviewed all the evidence filed to-date in this case, only evidence related to severity will be discussed herein, though other facts may be provided as necessary.

- On July 27, 2021 two months post vaccination Petitioner had an appointment with his PCP to follow up for unrelated (and pre-existing) illnesses. Ex. 2 at 76. Petitioner complained of "signif [sic] shoulder pain on right[,]" for which he "would like to see [physical therapy ("PT")]." *Id.* at 77. The note also states "[v]accinated." *Id.* The visit notes do not contain descriptions of a musculoskeletal examination. *Id.*
- Petitioner had a visit with an orthopedist on August 13, 2021, for "complaints of right shoulder pain." Ex. 4 at 64. Petitioner reported that his "sx [sic] began after he got his tetanus shot in his right shoulder 2 months ago." Id. He was "[u]nable to lift the arm overhead or extend behind due to pain." Id. A physical examination of the right shoulder confirmed restricted range of motion ("ROM") with flexion and abduction, tenderness to palpation of the right deltoid, and positive impingement signs. Id. at 66. Petitioner was assessed with "[r]ight shoulder pain in setting of tetanus vaccine possible SIRVA, [rotator cuff] tendinopathy/impingement, early signs of adhesive capsulitis." Id. at 63. He was referred to PT. Id.
- On August 27, 2021, Petitioner had his initial PT evaluation. Ex. 6 at 2. Petitioner reported the "date of injury to be 2 months ago after an injection." Id. He rated his pain at a 4-8/10 (best to worst) and described the frequency as "intermittent, daily" with a "sharp, aching" quality. Id. at 3. A physical examination showed reduced ROM. Id. Petitioner's diagnoses included "unspecified disorder of synovium and tendon, right shoulder[;] adhesive capsulitis of right shoulder[;] pain in right shoulder[; and] stiffness of right shoulder." Id. at 2. Additional PT was recommended. Id.
- Petitioner followed up with his orthopedist on September 2, 2021. Ex. 4 at 54. He noted he began PT and "has noticed some improved [ROM] but still quite bothersome." *Id.* Petitioner exhibited decreased ROM upon examination. *Id.* at 55. The plan was for Petitioner to continue PT and to use Voltaren gel. *Id.* at 54.
- Later that month, on September 28, 2021, Petitioner returned to his orthopedist reporting he had been attending one session of PT per week, but he felt "his progress ha[d] somewhat plateued [sic]." Ex. 4 at 44. Despite this feeling, Petitioner's "[right] shoulder ROM continue[d] to be limited." Id. Petitioner's physical examination revealed restricted ROM and positive impingement signs. Id. at 45. Petitioner received a steroid injection in his right shoulder; he was told to continue PT and return for imaging if his symptoms did not improve or worsened. Id. at 42-43.

- One month later, on October 28, 2021, Petitioner had a telehealth follow up with his PCP for unrelated illnesses. Ex. 2 at 89. During this visit, Petitioner noted that he was "getting PT for shoulder and had injection. Overall improved." Id.
- Petitioner attended his 15th and final PT session on November 19, 2021. Ex. 6 at 66. On that date, Petitioner rated his pain at a 4/10 at best and 6/10 at worst. *Id.* He continued to describe his pain as intermittent, daily, sharp, and aching. *Id.* Despite these entries, Petitioner reported "no new complaints," and he "tolerated [the] last session well with no increase in symptoms." *Id.* The physical therapist noted that Petitioner was "able to perform exercises with difficulty but no pain . . . manual treatment to restore shoulder ROM continued" and Petitioner exhibited "significant muscle guarding." *Id.* at 68. Regarding Petitioner's PT goals, the physical therapist documented that roughly 25-50% had been met. *Id.* at 68-69. The plan was for Petitioner to continue treatment with PT. *Id.* at 69. Petitioner did not return to PT for his right shoulder symptoms, however.
- Between December 2021 and April 2022, Petitioner had six medical visits, during which he did not mention right shoulder complaints. See, e.g., Ex. 4 at 34 (a February 8, 2022 orthopedic visit for bilateral knee pain); Ex. 2 at 96 (a February 28, 2022 PCP follow up visit for pre-existing conditions); Ex. 4 at 23 (a March 10, 2022 orthopedic visit for bilateral knee pain); Ex. 4 at 13 (a March 31, 2022 orthopedic visit for bilateral knee pain); Ex. 7 at 9 (an April 7, 2022 ophthalmology visit).
- In his affidavit, authored on August 16, 2023, Petitioner attests that he found PT to be ineffective at providing relief for his pain. Ex. 10 ¶ 4. At the time he finished PT in November 2021, Petitioner explains he was "still having pain and limited [ROM]." *Id.* ¶ 5. He also states that the relief from the steroid injection "lasted for a few days." *Id.* ¶ 4. Petitioner attests that "[s]ince receiving the Tdap vaccine, [his] right shoulder has not been the same[,]" to the point that his daily pain "is almost as bad [] as it was when [his] symptoms first began." *Id.* ¶ 5. He states that he takes meloxicam for his bilateral knee pain, but it is "not effective for [his] continued right shoulder pain." *Id.*

The Vaccine Act requires that a Petitioner demonstrate that "residual effects or complications" of a vaccine related injury continued for more than six months. Vaccine Act § 11(c)(1)(D)(i). A petitioner cannot establish the length or ongoing nature of an injury

merely through self-assertion unsubstantiated by medical records or medical opinion. § 13(a)(1)(A). To satisfy the six-month requirement, "[a] potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute." *Faup v. Sec'y of Health & Hum. Servs.*, No. 12-87V, 2015 WL 443802, at *4 (Fed. Cl. Spec. Mstr. Jan. 13, 2015). Rather, a petitioner is required to "submit supporting documentation which reasonably demonstrates that the alleged injury or its sequelae lasted more than six months[.]" *Id.*

Additionally, "the fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury." *Morine v. Sec'y of Health & Hum. Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); *see also Herren v. Sec'y of Health & Hum. Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (finding that a petitioner suffered from residual symptoms that due to their mild nature did not require medical care and thus that "a discharge from medical care does not necessarily indicate there are no residual effects"). In another SPU case, where a petitioner's last treatment was at five months and nine days, the petitioner was found to meet the six-month requirement. *Schafer v. Sec'y of Health & Hum. Servs.*, No. 16-0593V, 2019 WL 5849524 (Fed. Cl. Spec. Mstr. Aug. 28, 2019). In that case, based on the petitioner's symptomology and progression, the special master noted that it was unlikely "that petitioner's shoulder symptoms would have resolved within [the next] 22 days." *Id.* at *7.

In this case, there appears to be no dispute that Petitioner received the Tdap vaccine on May 28, 2021, and I will assume *arguendo* that the onset of Petitioner's symptoms occurred the day he received the subject vaccination, or at least within 48 hours.⁴ He therefore must demonstrate by preponderant evidence that his residual symptoms continued for more than six months thereafter from onset, or through November 28, 2021. *See,* e.g., *Herren,* 2014 WL 3889070, at *3.

The above medical entries clearly establish that on November 19, 2021, merely *nine* days shy of the severity "cut-off," Petitioner was still experiencing pain rated at a 4-6/10, muscle guarding with movements, and had only reached 25-50% of his PT goals. Ex. 6 at 66-69. On this date, the physical therapist did not state that Petitioner had improved completely, but instead that he did not have an "*increase* in symptoms." *Id.* at

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months ago after an injection.").

⁴ At this time, Respondent has not explicitly disputed that the onset of Petitioner's vaccine-related injury occurred within 48 hours of the subject Tdap vaccination. *See generally*, Respondent's Report at 4-7. While this fact ruling does not address or determine whether the onset of Petitioner's post-vaccination shoulder symptoms meets the Act's Table SIRVA requirements, I will note that some of the medical records contain entries placing onset in June 2021 – thus not within 48 hours of vaccination. *See*, e.g., Ex. 4 at 64 (an August 13, 2021 note that Petitioner's symptoms "began after he got his tetanus shot in his right shoulder 2 months ago."); Ex. 6 at 2 (an August 27, 2021 note that Petitioner reported the "date of injury to be 2

66 (emphasis added). Accordingly, additional PT was recommended to address these ongoing symptoms. *Id.* at 69. These record notations, paired with a proposed continued treatment course, provide evidence that Petitioner's injury was at this point ongoing, and that his treating physician did not predict that the injury was likely to resolve soon thereafter – or even within the next nine days. *See*, e.g., *Schafer*, 2019 WL 5849524, at *7.

I also do not construe Petitioner's cessation of treatment as evidence that his injury had resolved before the six-months date post-onset. Rather, Petitioner's treatment cessation has a reasonable explanation (that he was not experiencing relief from PT), and thus does not support the conclusion that the SIRVA had completely resolved by that time. *Compare* Ex. 6 at 68-69 (the November 19, 2021 PT record showing 25-50% of Petitioner's goals had been met), *with* Ex. 10 ¶ 4 (stating Petitioner's PT was "ineffective in providing relief."). While Petitioner sought treatment soon thereafter for other, non-shoulder related issues, including with his orthopedist and PCP, the fact that he did not complain of shoulder symptoms during those visits, does not preclude Petitioner from establishing severity – as the visit notes from his last encounter show lingering pain and ROM restrictions.

Compared to other SIRVA injuries, however, Petitioner's right shoulder pain and limited ROM was not especially severe, improving with fairly conservative treatment. Yet, the mildness of Petitioner's symptoms is a matter that goes to the ultimate quantum of damages to be paid. The fact that his injury was not acute or lengthy does not prevent the determination that it nevertheless lingered long enough to satisfy severity under the Vaccine Act. Overall, such circumstances produce, at worse, a "tie" in evidence that should be decided in Petitioner's favor. *Roberts v. Sec'y of Health & Hum. Servs.*, No. 09-427V, 2013 WL 5314698, at *10 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (noting petitioners are afforded the benefit of close calls in the Vaccine Program).

IV. Scheduling Order

Respondent shall file, by no later than <u>Friday</u>, <u>October 04</u>, <u>2024</u>, a status report concerning how he intends to proceed, including, if appropriate, whether he would like to file an amended Rule 4(c) report.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master